

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

HARVEY H. JAY, M.D.,

Plaintiff,

v.

No. 1:13-cv-8137-LTS-DCF

SPECTRUM BRANDS HOLDINGS, INC.,
SPECTRUM BRANDS, INC., and
SHASER, INC.,

Defendants.

**PLAINTIFF'S REPLY BRIEF IN FURTHER SUPPORT OF
PLAINTIFF'S PROPOSED CLAIM CONSTRUCTION**

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Table of Contents

I.	INTRODUCTION.....	1
II.	MANY ISSUES RAISED IN DEFENDANTS’ BRIEF ARE IRRELEVANT TO CLAIM CONSTRUCTION	1
III.	THE DISPUTED CLAIM TERMS SHOULD BE CONSTRUED ACCORDING TO THEIR ACCUSTOMED MEANING IN THE ART	2
A.	Defendants Fail To Overcome The “Heavy Presumption” That The Claims Mean What They Say	2
B.	Dr. Jay’s Explanations Of Differences Between His Work And Others’ Are Not “<i>Words or Expressions of Manifest Exclusion or Restriction</i>” Of The Subject Matter Claimed	4
IV.	DEFENDANTS’ ARGUMENTS RELATING TO “CLASSES” OF DCTs SHOULD BE REJECTED, AS SHOULD DEFENDANTS’ PROPOSED CONSTRUCTIONS.....	5
A.	Defendants Fail To Couple Their Arguments With Their Proposed Constructions Of The Disputed Claim Terms (DCTs).....	5
B.	Defendants Present A Diagram Which Misrepresents The Hair Follicle	6
C.	Observations Regarding The Five “Classes” Of DCTs Proposed By Defendants	8
	(1) “Temporarily Preventing” (or “Removing” or “Maintaining”)	8
	(2) “Retarding” (or “Slowing,” “Delaying”) Hair Growth.....	9
	(3) “Predetermined” (Pulses, Total Energy) and “Applying”	10
	(4) “Hair Severing”.....	10
	(5) “Repeat Treatment Before Hair Growth”.....	12
D.	Plaintiff’s Proposed Construction Of DCT 17 Requires Clarification	13
E.	Defendants’ Proposed Construction Of DCT 26 Appears To Bear No Relation To The DCT	14
V.	CONCLUSION	14

Table of Authorities

Cases

<i>Home Diagnostics Inc. v. LifeScan Inc.</i> , 381 F.3d 1352 (Fed. Cir. 2004)	3, 4
<i>Johnson Worldwide Assoc. Inc. v. Zebco Corp.</i> , 175 F.3d 985 (Fed. Cir. 1999)	3
<i>Phillips v. AWH Corp.</i> , 415 F.3d 1303 (Fed. Cir. 2005) (<i>en banc</i>), <i>cert. denied</i> , 546 U.S. 1170 (2006)	3
<i>Renishaw PLC v. Marposs Societa Per Azioni</i> , 158 F.3d 1243 (Fed.Cir. 1998)	2
<i>SanDisk Corp. v. Memorex Prods., Inc.</i> , 415 F.3d 1278 (Fed. Cir. 2005)	3
<i>Teleflex Inc. v. Ficosa North America Corp.</i> , 299 F.3d 1313 (Fed. Cir. 2002)	3

Other Authorities

Proceedings of the National Academy of Sciences of the United States of America ("PNAS"), "Diagram of the hair follicle and cell lineages supplied by epidermal stem cells." Published online before print August 11, 2003, doi: 10.1073/pnas.1734203100 PNAS September 30, 2003; vol. 100 no. suppl 1 11830-11835. Available at http://www.pnas.org/content/100/suppl_1/11830/F2.expansion.html (retrieved Oct. 9, 2014)	6
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I. INTRODUCTION

Plaintiff Harvey H. Jay, *M.D.*, (“Plaintiff” or “Dr. Jay”) hereby submits this Reply Brief (the “Reply”), as well as the Declaration of Gary D. Colby, and Appendix “A” thereto, submitted herewith, in response to the issues raised by Spectrum Brands Holdings, Inc., Spectrum Brands, Inc., and Shaser, Inc., (collectively, “Defendants” or “Spectrum”) in their Responsive Claim Construction Brief (“Defendants’ Brief”), and in further support of Plaintiff’s Proposed Claim Construction.

II. MANY ISSUES RAISED IN DEFENDANTS’ BRIEF ARE IRRELEVANT TO CLAIM CONSTRUCTION

After requesting an expansion of the Court’s page limits for Defendants’ Brief, Defendants consumed a dozen or more pages of that brief discussing many issues that are irrelevant to the claim construction issues presently before the Court. Among those issues are the following:

1. Whether one or more of the Asserted Claims is invalid;
2. Whether one or more of the Asserted Patents is unenforceable owing to alleged inequitable conduct;
3. Whether Plaintiff reduced his inventions to practice other than by fully describing them in patent applications that subsequently issued as patents;
4. Whether Plaintiff changed patent attorneys during the process of prosecuting his patent applications;
5. The contents of the prior art;
6. The priority date(s) to which one or more Asserted Claims may be entitled;

7. Whether one or more of Plaintiff's patents discloses more subject matter than is encompassed by its corresponding claims; and
8. Whether one or more of the Asserted Claims is "defective."

Owing to the page limits for this Reply, and the inappropriateness of briefing these issues during the claim construction phase of this litigation, Plaintiff declines to address these issues in this Reply, but reserves the right to respond to each said issue if and when it is raised during an appropriate phase of this litigation, or if ordered to do so by the Court.

III. THE DISPUTED CLAIM TERMS SHOULD BE CONSTRUED ACCORDING TO THEIR ACCUSTOMED MEANING IN THE ART

Defendants' Brief includes numerous quotations excerpted from the prosecution histories of the Asserted Patents. The Defendants characterize those quotations as evidence that the Court should limit the scope of the Asserted Claims by adopting Defendants' proposed constructions of the DCTs. However, because the excerpted quotations relate to Dr. Jay merely explaining to a patent examiner how methods used by others differ from the methods Dr. Jay invented and claimed, those explanations do not evince intent by Dr. Jay to limit the scope of his claims, and Defendants' characterizations of those explanations do not overcome the presumption that the Asserted Claims mean what they say.

A. Defendants Fail To Overcome The "Heavy Presumption" That The Claims Mean What They Say

Interpretation of a claim by a court begins with the words of the claim.¹ The general rule of claim interpretation is that a term used in a patent claim is given its ordinary and customary meaning, which is "the meaning the term would have to a person of ordinary skill in the art in

¹ *Renishaw PLC v. Marposs Societa Per Azioni*, 158 F.3d 1243, 1248-9 (Fed.Cir. 1998).

question at the time of the invention, i.e., as of the effective filing date of the patent application.”² “[N]ormal rules of usage create a ‘heavy presumption’ that claim terms carry their accustomed meaning...”³ In other words, a Court must presume that a term in a claim means what it says and give full effect to the ordinary meaning of the term unless the Court is compelled otherwise.⁴ A claim term must be interpreted by the Court consistently with any statements or arguments in the prosecution history which: (a) were made by the patentee; and (b) clearly and unmistakably limit the interpretation of the term.⁵ However, “*Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language.*”⁶ In order to make such a clear disavowal of claim scope in the prosecution history, a patentee must “*characterize[] the invention using words or expressions of manifest exclusion or restriction.*”⁷

The quotations from the prosecution histories of the Asserted Patents that are offered in Defendants’ Brief do not evidence any intention on the part of the patentee and Plaintiff, Dr. Jay, to surrender claimed subject matter.

² *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (*en banc*), *cert. denied*, 546 U.S. 1170 (2006).

³ *Home Diagnostics Inc. v. LifeScan Inc.*, 381 F.3d 1352, 1355 (Fed. Cir. 2004).

⁴ *Johnson Worldwide Assoc. Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999).

⁵ *SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1286 (Fed. Cir. 2005); *see also, Teleflex Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002) (“We hold that claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term ... by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.”)

⁶ *Home Diagnostics*, 381 F.3d at 1358.

⁷ *Teleflex*, 299 F.3d at 1326 (“the prosecution history may demonstrate that the patentee intended to deviate from a term’s ordinary and accustomed meaning, *i.e.*, if it shows the applicant characterized the invention using words or expressions of manifest exclusion or restriction during the administrative proceedings before the Patent and Trademark Office.”)

B. Dr. Jay's Explanations Of Differences Between His Work And Others' Are Not "*Words or Expressions of Manifest Exclusion or Restriction*" Of The Subject Matter Claimed

In Defendants' Brief, the Defendants reproduce selected excerpts from explanations offered by Dr. Jay to the Patent and Trademark Office about differences between methods used previously by others and the various methods which Dr. Jay sought to patent in the corresponding patent applications. Not surprisingly, differences in the methods previously used by others bore a relation to, and were understandable in light of, the nature of the work being performed by those others. Dr. Jay's explanations pertain, at least in part, to explaining to the Examiner why those previous workers lacked motivation to modify their prior methods to arrive at the methods Dr. Jay invented and patented.

Glaringly absent from any of the excerpts selected for the Defendants' Brief are "*words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.*"⁸ The Defendants' Brief does not clearly indicate how or why Dr. Jay's explanations of the differences between:

- i) the methods he invented and claimed; and
- ii) methods previously used by others

should be treated as a "*clear disavowal of claim scope*"⁹ for any of the DCTs. Mere discussion of differences between prior art and a claimed invention does not, by itself, amount to a disavowal of claim scope.

Because the Defendants have failed to demonstrate that statements made by Dr. Jay during prosecution of the Asserted Patents manifested an intent on his part to exclude or restrict subject matter from the Asserted Claims, the Court should rely on the "heavy presumption" that

⁸ *Id.*

⁹ *Home Diagnostics*, 381 F.3d at 1357.

the claims mean what they say. That is, the Court should adopt the accustomed meanings of the DCTs set forth in the Plaintiff's Opening Claim Construction Brief.

IV. DEFENDANTS' ARGUMENTS RELATING TO "CLASSES" OF DCTs SHOULD BE REJECTED, AS SHOULD DEFENDANTS' PROPOSED CONSTRUCTIONS

Defendants' Brief presents (see "Addendum A") proposed constructions of DCTs that are uncoupled from "classes" of DCTs proposed and generically discussed in the remainder of the brief. Defendants' Brief also presents a misleading diagram as a technical background for understanding the arguments presented therein. Both because of Defendants' failure to map their arguments to their proposed constructions and because of shortcomings in those arguments themselves, Defendants' proposed constructions of the DCTs should be rejected.

A. Defendants Fail To Couple Their Arguments With Their Proposed Constructions Of The Disputed Claim Terms (DCTs)

In Section V of Defendants' Brief, the Defendants propose five "classes" of DCTs; nominate "representative" (according to unknown standards) DCTs for each class; discuss various issues purportedly relevant to each class; and then present a conclusory list of proposed constructions for the 30 DCTs in an "Addendum A" that follows Defendants' Brief. Plaintiff (and, evidently, the Court) are left to connect the dots – if, indeed, Defendants' arguments can be coupled with their proposed constructions at all. The Plaintiff respectfully contends that the Defendants' vague discussions of arbitrarily selected "representative" DCTs in proposed "classes" of such DCTs, coupled with a list of proposed constructions for those DCTs clearly fails to overcome the "heavy presumption" that the claims mean what they say.

B. Defendants Present A Diagram Which Misrepresents The Hair Follicle

The diagram included on page 4 of Defendants' Brief is a figure of unknown origin which purports to depict "Hair Anatomy." However, this figure is misleading and incomplete. The figure included in Defendants' Brief only shows stem cells adjacent the hair shaft, but omits important features necessary to understand the work of Dr. Jay and others. Defendants seek to characterize Dr. Jay's explanations to a patent examiner of ways in which the work of others differed from his in the context of the misleading figure included in Defendants' Brief.

Annexed to the Declaration of Gary D. Colby ("Colby Decl.") as Appendix "A" thereto, submitted herewith, and incorporated by reference herein, is a diagram obtained from an identified public source.¹⁰ The diagram is offered merely as an illustration of a typical hair follicle. As seen in this diagram, the hair shaft extends from the dermal papilla beneath the skin surface.¹¹ From this diagram, it can be seen that a hair follicle is not simply a "tubular structure" (as described in the Defendants' Brief), but instead contains several regions. In addition to the generally tubular inner and outer root sheaths which surround the hair shaft beneath the skin surface, the follicle also includes several accessory structures, including a generally bulbular hair follicle matrix ("hair bulb" in the diagram in Defendants' Brief) and one or more sebaceous glands.

Significantly, the hair follicle also includes a "bulge" region in which "stem cells" can be found and from which those stem cells can migrate either toward the skin surface or toward the hair bulb. "Stem cells" refers generally to cells which are able to reproduce themselves

¹⁰ See Colby Decl., at Appx. "A." Proceedings of the National Academy of Sciences of the United States of America ("PNAS"), "Diagram of the hair follicle and cell lineages supplied by epidermal stem cells." Published online before print August 11, 2003, doi: 10.1073/pnas.1734203100 PNAS September 30, 2003; vol. 100 no. suppl 1 11830-11835. Available at http://www.pnas.org/content/100/suppl_1/11830/F2.expansion.html (retrieved Oct. 9, 2014).

¹¹ The skin surface is the 'top' or exterior portion of the structure identified in the diagram as "epidermal layers."

continuously, typically throughout a person's life. It is the stem cells which are believed to permit an injured or inactive hair follicle to regenerate itself and commence growing a new hair. Existence and location of the stem cells within a hair follicle are believed to be among the factors which will determine whether a treatment applied to a hair follicle will have permanent or temporary effects.

The diagram included in Defendants' Brief misleadingly shows all stem cells aligned along and generally in close proximity to the hair shaft. This diagram would lead one to believe that phenomena (e.g., absorption of intense light) which cause damage to the hair shaft would necessarily or very likely damage all stem cells as well. The diagram submitted herewith as Appendix "A" illustrates that stem cells originating in the bulge region can be found in several portions of the hair follicle at which they are not in close proximity to the hair shaft and where they may be unaffected by phenomena which damage the hair shaft. Survival of such stem cells can, for example, significantly affect whether a phenomenon causes permanent or temporary hair loss at a hair follicle.

Although thorough understanding of these concepts is not critical to the Court's present task of construing DCTs, the Plaintiff believes that the diagram submitted with Defendants' Brief omits structures and elements necessary for a full understanding of the issues discussed in this Brief and in Defendants' Brief.

Against this technical background, the Plaintiff now discusses the arguments presented by the Defendants in connection with the "classes" of DCTs proposed in Defendants' Brief.

C. Observations Regarding The Five “Classes” Of DCTs Proposed By Defendants

In this section, the Plaintiff presents comments pertaining to the five “classes” of DCTs proposed for the first time in Defendant’s Brief. (*See* Defendant’s Brief, at Sections V.A-E).

(1) “Temporarily Preventing” (or “Removing” or “Maintaining”)

The Defendants reproduce selected excerpts from explanations offered by Dr. Jay to the U.S. Patent Office about differences between methods used previously by others and the various methods which Dr. Jay sought to patent in the corresponding patent applications. Among the explanations excerpted in Defendants’ Brief are portions of discussions in which Dr. Jay explains why and how the research objectives (i.e., the likely thought processes of the authors of various publications cited by the patent examiner) would lead them away from altering their methods to make them more like the methods that Dr. Jay sought to claim. Defendants’ Brief (see, e.g., p. 29, first non-bulleted paragraph) appears to suggest that these explanations demonstrate that Dr. Jay intended to admit that a person does not practice Dr. Jay’s claimed methods if that person “thinks the wrong thoughts” – *i.e.*, that if a person holds the ‘wrong’ thoughts, goals, or objectives in his mind or heart, then that person does not practice Dr. Jay’s method, even if that person practices precisely the method that Dr. Jay claims. Apart from being logically preposterous, Defendants’ proposed conclusion that Dr. Jay intended to create a “thought exclusion” from infringement of his claimed methods does not follow from the excerpted portions of Dr. Jay’s explanations to the patent examiner.

The Court should decline Defendants’ apparent suggestion that the DCTs be limited to require or exclude “thoughts,” “goals,” and “intentions.” Each of the constructions proposed by Defendants for DCTs 1, 11, and 14-17 include such “thought limitations,” and Defendants’ proposed constructions of DCTs 9, 13, and 18 are also referenced in the same section of

Defendants' Brief. Each of Defendants' proposed constructions for DCTs 1, 9, 11, and 13-18 should be rejected for the reasons discussed in this section.

(2) “Retarding” (or “Slowing,” “Delaying”) Hair Growth¹²

Defendants advance the curious argument that “slowing” cannot include (even temporarily) reducing a rate to zero. Application of simple common sense shows the folly of this argument.

As anyone who has driven an automobile can attest, the rate at which one arrives at one's destination can be influenced by a number of factors, including traffic signs and signals, some of which occasionally require drivers to stop (*i.e.*, reduce their rate of travel to zero). Applying Defendants' logic, one's automobile travel cannot be “slowed” by traffic signs and signals (because this would temporarily reduce the rate to zero). In the real world, of course, drivers consider their progress “slowed” by stoplights and stop signs. Similarly, hair growth can be “slowed, delayed, or retarded” if hair growth is temporarily reduced to a rate of zero. There is no logical basis for the applying Defendants' argument to limit the DCTs in any manner.

Defendants' failure to couple their arguments with particular DCTs requires the Plaintiff (and the Court) to speculate as to which, if any, DCTs Defendants' argument is intended to apply. It appears to the Plaintiff that Defendants' argument is applied to DCTs 10, 28, and 29, and Defendants' Brief references DCTs 19 and 26 in the same section. Each of Defendants' proposed constructions for DCTs 10, 19, 26, 28, and 29 should be rejected for the reasons discussed in this section.

¹² The “defective claim” issue raised in section V.B.2.a) of Defendants' Brief is among the issues listed above in section II of this brief as being not relevant to claim construction or replied to in this Brief.

(3) “Predetermined” (Pulses, Total Energy) and “Applying”

Defendants’ Brief takes the Plaintiff to task for suggesting that the predetermination referred to in the word “predetermined” is made prior to the time at which light pulses are applied, rather than prior to the time at which light pulses are generated. The Plaintiff acknowledges switching words, but observes that the two times are substantially identical: light pulses (both in the claimed methods and in the accused devices) are generated and applied at the same time. To the extent that there is any difference between the two times, it is infinitesimal.¹³ The Plaintiff therefore contends that Plaintiff’s shift in terminology is harmless at worst.

(4) “Hair Severing”

On page 38 of Defendants’ Brief, the Defendants appear to suggest that Plaintiff “admitted” that “protruding” and “projecting” hair fibers are “the same thing.” Plaintiff has admitted no such thing, as Plaintiff’s Opening Claim Construction Brief clearly demonstrates. The diagram of a hair follicle submitted herewith as Appendix “A” illustrates that a hair shaft which extends from its source in a hair follicle need not extend beyond the skin surface (*e.g.*, a newly-growing hair does not suddenly “pop into existence” extending from the hair root, through the length of the follicle, through the follicular opening, and beyond the surface of the skin, but instead grows from the root, gradually filling the follicle, later extending through the follicular opening, and – if growth continues long enough – it continues extending beyond the skin surface).

¹³ In fact, the time difference would be the time required for light to traverse the few millimeters of distance between the light source and the target(s) which absorb light in the skin. Given that light travels at roughly 300 billion millimeters per second in a vacuum (and only slightly slower in air), it is apparent that the time difference between light generation and light application is infinitesimal – on the order of a few ten-billionths of a second.

In Section D.2.a) of Defendants' Brief, Defendants reproduce excerpts from the prosecution histories of the Asserted Patents, wherein the Plaintiff observes that other researchers removed hair by shaving (and not by applying light). Defendants cite these excerpts as an apparent rationale for limiting one or more of the Asserted Claims in some unspecified way.¹⁴ On their face, these excerpts do not include any "*words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.*"¹⁵ The Court should discount these arguments.

In Section D.2.b) of their brief, Defendants present selected excerpts from the prosecution histories of the Asserted Patents in which the Plaintiff explains differences between his claimed methods and methods used by others, including the fact that methods used by others were designed to focus their effects upon hair follicle cells, rather than on hairs. Indeed, this explanation appears in each of the Asserted Patents. For example, the '308 Patent states, in relevant part:

Thus, in contrast to prior methods, which are aimed at completely destroying the hair follicle and terminating hair growth (and which may require the application of exogenous chromophores to the target skin surface), the present method contemplates only a partial destruction of the follicles or, alternatively, a destruction of the hair inside the follicles. '308 Patent, col. 6, ll. 39-45.

Defendants contend that the Plaintiff's explanation that others focused their efforts on methods which specifically target hair follicles means that the Plaintiff's claimed methods cannot affect hair follicles at all. Such a contention is contrary to the meaning of the excerpts selected by the

¹⁴ As with other such arguments in Defendants' Brief, the Plaintiff (and the Court) are left to figure out how, if at all, Defendants' arguments correspond to construction of one or more DCTs.

¹⁵ *Id.*

Defendants when considered in the context of the documents from which they were excerpted. That contention is also directly contrary to the specifications of the Asserted Patents, as exemplified in the excerpt reproduced above. However, above all, the Plaintiff's efforts to help the patent examiner to understand differences between the Plaintiff's claimed methods and efforts by previous worker do not include "*words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope*"¹⁶ that the Court must find to be present in order to treat the Plaintiff's explanatory comments as claim limitations.

As with other arguments in the Defendants' Brief, the Plaintiff (and the Court) are left to "connect the dots" to link these arguments with Defendants' proposed constructions of DCTs. From what Plaintiff can surmise, the arguments presented in these sections of the Defendants' Brief appear to factor into the Defendants' proposed constructions of DCTs 4, 5, 9, 10, 18, 24-28, and 30. Defendants' Brief references DCT 6 in the same section. Each of Defendants' proposed constructions for DCTs 4-6, 9, 10, 18, 24-28, and 30 should be rejected for the reasons discussed in this section.

(5) "Repeat Treatment Before Hair Growth"

The Plaintiff is unable to comprehend the logic of the argument in Defendants' Brief (*see* page 42, first full paragraph) to the general effect that the Plaintiff is attempting to encompass some sort of a failed attempt to achieve permanent hair removal within the scope of the Asserted Claims. The Plaintiff accordingly denies that any such attempt is being made.

Defendants' Brief references DCTs 7, 8, and 25 in this section. Defendants' proposed constructions of DCTs 7, 8, and 25 each refer to reappearance of hair fibers "that were removed"

¹⁶ *Id.*

and appear to envision that removed hairs will somehow find their way back to the skin and reappear there. Without speculating as to where such hairs might be proposed to lurk between the time they are removed and a time at which they later reappear (or as to whether such removed hairs are proposed to creep, fly, or teleport back to the skin to achieve such reappearance), the Plaintiff respectfully suggests that Defendants' proposed constructions of DCTs 7, 8, and 25 is nonsensical and should be rejected by the Court.

D. Plaintiff's Proposed Construction Of DCT 17 Requires Clarification

In Defendants' Brief (p. AA-5, item 17), Defendants object that Plaintiff altered his proposed construction of DCT 17 ("For the Temporary Removal of Hair") relative to that which appeared in the Parties' Joint Claim Terms Chart (the "JCTC").¹⁷ Reviewing Plaintiff's Opening Claim Construction Brief (page 22), the Plaintiff notes that the proposed construction offered for DCT 17 was inadvertently truncated. As indicated in Plaintiff's Opening Claim Construction Brief (page 22), DCT 17 is simply a combination of DCT 1 ("temporarily") with the remaining words of DCT 17. That combination is clarified here as it should have appeared in Plaintiff's Opening Claim Construction Brief, as is clear from the context identified above.

17. "For the Temporary Removal of Hair"

Proposed Construction:	"For the non-permanent removal of hair"
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¹⁷ Whether Plaintiff's proposed constructions of DCTs differed (as did Defendants' proposed constructions of DCTs) from those which appeared in the JCTC is another issue (in addition to those listed on p. 1 of this Brief) that is not relevant to claim construction and to which the Plaintiff declines to substantively reply in this Brief, owing to page restrictions and the irrelevance of the issue to the task before the Court.

The Court is respectfully requested to consider this proposed construction of DCT 17 as a clarification of the proposed construction that was inadvertently truncated in Plaintiff's Opening Claim Construction Brief.

E. Defendants' Proposed Construction Of DCT 26 Appears To Bear No Relation To The DCT

DCT 26 relates to slowing the rate of hair growth (and variations of those terms). Defendants' proposed construction of DCT 26 refers to removal of hair fibers and addresses neither the rate of hair growth or any slowing thereof. Defendants' proposed construction of DCT 26 should therefore be rejected.

V. CONCLUSION

For the foregoing reasons, Plaintiff Harvey H. Jay, M.D., respectfully requests that the Court adopt each of Plaintiff's Proposed Constructions of the Disputed Claim Terms, including the clarification made herein to DCT 17.

Respectfully submitted,

Dated: October 9, 2014

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